

AUG 1 0 2001

**NORTECH**

K011928

## SUMMARY OF SAFETY AND EFFECTIVENESS

**Common/Usual Name:** Arthroscope and Accessories

**Proprietary Name:** Hydrotower® Arthroscopic Administration Tubing Set

**Classification:** Class II

**Materials:**

Materials used to manufacture the Nortech® Hydrotower® Arthroscopic Administration Tubing Set are non-toxic and have been previously used to manufacture other devices.

**Description:**

The Hydrotower® Arthroscopic Administration Tubing Set is designed to be used with the Nortech® Hydrotower® System. The device is comprised of pvc tubing, check valve, a pressure relief valve, and numerous polymer fittings.

**Substantial Equivalence:**

Northgate's Hydrotower® Arthroscopic Administration Tubing Set is a tubing set that is substantially equivalent in design materials, and intended use to numerous currently marketed devices. Northgate manufactures similar devices as indicated in Exhibits # 1/ # 2.

**Intended Use:**

The Nortech® Hydrotower® Arthroscopic Administration Tubing Set shall be used to move fluid from the tower bag to the patient.



AUG 1 0 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Casey Kurek  
Regulatory Manager  
Northgate Technologies, Inc.  
600 Church Road  
Elgin, Illinois 60123

Re: K011928

Trade/Device Name: The Hydrotower® Arthroscopic Administration Tubing Set  
Regulation Number: 880.5440, 876.1500  
Regulatory Class: II  
Product Code: FPA, GCJ  
Dated: June 18, 2001  
Received: June 20, 2001

Dear Mr. Kurek:

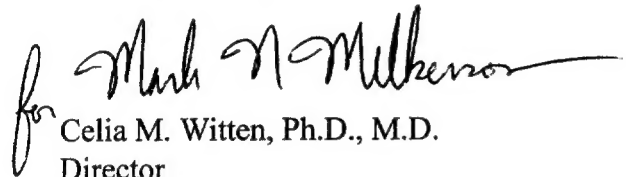
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.  
Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



**CONFIDENTIAL**

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510 (k) Number (If known): K011928

Device Name: THE HYDROTOWER® ARTHROSCOPIC ADMINISTRATION TUBING SET

Indications For Use:

THE HYDROTOWER® ARTHROSCOPIC ADMINISTRATION TUBING SET IS USED TO MOVE FLUID FROM THE TOWER BAG TO THE PATIENT.

  
C. Kurek, Regulatory Manager

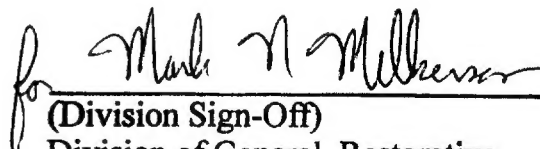
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

(Optional Format 1-2-96)

510(k) Number K011928